



1614
PATENT
674543-2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Morton et al.
Serial No. : 10/668,564
Filed : September 23, 2003
For : LIPID PROFILE MODULATION
Group Art Unit : 1614

745 Fifth Avenue
New York, NY 10151

EXPRESS MAIL

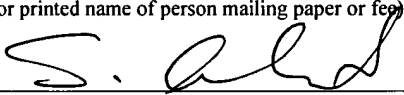
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Dear Sir:

The Examiner's attention is respectfully drawn to the enclosed documents listed on the accompanying PTO Form 1449.

As this Information Disclosure Statement is being filed before the mailing of the first Office Action, it is believed that no fee is required for entry of this paper. However, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account 50-0320.

The filing of this Information Disclosure Statement is not an admission that the documents identified herein constitute prior art to the present application.

Applicants respectfully request that the Examiner considers and makes of record the documents cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

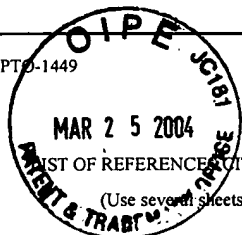
Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

A handwritten signature in cursive script, reading "Deborah L. Lu", is written over a horizontal line.

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Encs. PTO Form 1449
References (54)

Based on Form PTO-1449
(3/90)

LIST OF REFERENCES CITED BY APPLICANT

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,920,115	04/24/90	Nestler et al.			
	AB	4,518,595	05/21/85	Coleman et al.			
	AC						
	AD						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AE	WO 02/02797	01/10/02	WIPO				
	AF	WO 97/07789	03/06/97	WIPO				
	AG	WO 01/90092	11/29/01	WIPO				
	AH	EP 1 157 695	11/28/01	WIPO				
	AI	WO 02/072084	09/19/02	WIPO				
	AJ							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	AK	Hult, M. et al., "Selective Inhibition of Human Type 1 11 β -Hydroxysteroid Dehydrogenase by Synthetic Steroids and Xenobiotics," <i>FEBS Letters</i> , 441: 25-28, 1998 (XP-004258864)
	AL	Whorwood, C. et al., "Regulation of Glucocorticoid Receptor α and β Isoforms and Type 1 11 β -Hydroxysteroid Dehydrogenase Expression in Human Skeletal Muscle Cells: A Key Role in the Pathogenesis of Insulin Resistance," <i>JCE&M</i> , 86(5): 2296-2308, 2001 (XP-001149824)
	AM	McIntosh, M. et al., "Opposing Actions of Dehydroepiandrosterone and Corticosterone in Rats," <i>P.S.E.B.M.</i> , 221: 198-206, 1999 (XP-001148856)
	AN	Nestler, J. et al., "Dehydroepiandrosterone: the "Missing link" between Hyperinsulinemia and Atherosclerosis?" <i>FASEB J.</i> , 6: 3073-3075, 1992 (XP-001148845)
	AO	Richards, R. et al., "Serum Leptin, Lipids, Free Fatty Acids, and Fat Pads in Long-Term Dehydroepiandrosterone-Treated Zucker Rats," <i>P.S.E.B.M.</i> , 223: 258-262, 2000 (XP-008015883)
	AP	Tchernof, A. et al., "Relationships between Endogenous Steroid Hormone, Sex Hormone-Binding Globulin and Lipoprotein Levels in Men: Contribution of Visceral Obesity, Insulin Levels and Other Metabolic Variables," <i>Atherosclerosis</i> , 133: 235-244, 1997 (XP-002241940)
	AQ	Alexandersen, P. et al., "Natural Androgens Inhibit Male Atherosclerosis: A Study in Castrated, Cholesterol-Fed Rabbits," <i>Circ Res.</i> , 84: 813-819, 1999 (XP-001149840)
	AR	Smith, K. et al., "Peroxisomal Proliferator-Activated Ligand Therapy For HIV Lipodystrophy," <i>Clinical & Experimental Dermatology</i> , 26: 155-161, 2001 (XP-002241941)
	AS	Kurzman, I. et al., "The Effect of Dehydroepiandrosterone Combined with a Low-Fat Diet in Spontaneously Obese Dogs: A Clinical Trial," <i>Obesity Research</i> , 6(1): 20-28, 1998 (XP-008015881)
	AT	Berger, J. et al., "Peroxisome Proliferator-activated Receptor- γ Ligands Inhibit Adipocyte 11 β -Hydroxysteroid Dehydrogenase Type 1 Expression and Activity," <i>The Journal of Biological Chemistry</i> , 276(16): 12629-12635, 2001 (XP-001149395)

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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	BO						
	BP						

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)			
	BQ		Andrews, R. et al., "Glucocorticoids and Insulin Resistance: Old Hormones, New Targets," <i>Clinical Science</i> , 96: 513-523, 1999 (XP-001172422)
	BR		Diedrich, S. et al., "In the Search for Specific Inhibitors of Human 11 β -Hydroxysteroid Dehydrogenase (11 β -HSDs): Chenodeoxycholic acid selectively inhibits 11 β -HSD-I," <i>European J. of Endocrinology</i> , 142: 200-207, 2000 (XP-002226259).
	BS		Aoki, K. et al., "Dehydroepiandrosterone Suppresses the Elevated Hepatic Glucose-6-Phosphatase and Fructose-1,6-Bisphosphatase Activities in C57BL/Ksj-db/db Mice," <i>Diabetes</i> , 48: 1579-85, 1999 (XP-001150303)
	BT		Hansen, P. et al., "DHEA Protects Against Visceral Obesity and Muscle Insulin Resistance in Rats Fed a High-Fat Diet," <i>Am. J. Physiol.</i> , 273: R1704-08, 1997 (XP-008015768)
	BU		Hermanowski-Vosatka, A. et al., "PPAR α Agonists Reduce 11 β -Hydroxysteroid Dehydrogenase Type 1 in the Liver," <i>Biochemical and Biophysical Research Communications</i> , 279: 330-36, 2000
	BV		Rao, M. et al., "Dehydroepiandrosterone Inhibits DNA Synthesis of Rat Hepatocytes Induced by Partial Hepatectomy of Mitogen (Ciprofibrate)," <i>Cell Prolif.</i> , 30: 1-5, 1997 (XP-008015877)
	BW		Haffa, A. et al., "Hypocholesterolemic Effect of Exogenous Dehydroepiandrosterone Administration in the Rhesus Monkey," <i>In Vivo</i> , 8: 993-98, 1994 (XP-008015868)
	BX		Chance, D. et al., "Inverse Relationship Between Peroxisomal and Mitochondrial β -Oxidation in HepG2 Cells Treated with Dehydroepiandrosterone and Clofibrate Acid," <i>P.S.E.B.M.</i> , 208: 378-84, 1994 (XP-001148841)
	BY		Alexandersen, P. et al., "The Relationship of Natural Androgens to Coronary Heart Disease in Males: a Review," <i>Atherosclerosis</i> , 125: 1-13, 1996 (XP-002241942)
	BZ		Gordon, G. et al., "Reduction of Atherosclerosis by Administration of Dehydroepiandrosterone," <i>J. Clin. Invest.</i> , 82: 712-20, 1988 (XP-002049299)
	CA		Walker, B. et al., "Abnormal Glucocorticoid Activity in Subjects with Risk Factors for Cardiovascular Disease," <i>Endocrine Research</i> , 22(4): 701-8, 1996 (XP-008023578)
	CB		Morton, N. et al., "Improved Lipid and Lipoprotein Profile, Hepatic Insulin Sensitivity, and Glucose Tolerance in 11 β -Hydroxysteroid Dehydrogenase Type 1 Null Mice," <i>J. Biol. Chem.</i> , 276: 41293-300, 2001 (XP-001149394)
	CC		Database Accession No. NLM2522296 (XP-002241947)
	CD		Database Accession No. 69: 65726 (XP-002241948)
	CE		Database Accession No. NLM8597455 (XP-002241946)

EXAMINER <div style="text-align: center;">7</div>	DATE CONSIDERED. <div style="text-align: center;">5</div>
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	AW						
	AX						

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
AY		Sandeep, T. et al., "Pathophysiology of Modulation of Local Glucocorticoid Levels by 11 β -Hydroxysteroid Dehydrogenases," <i>TRENDS in Endocrinology & Metabolism</i> , 12(10): 446-453, 2001 (XP-001149392)
AZ		Coleman, D.L. et al., "Therapeutic Effects of Dehydroepiandrosterone (DHEA) in Diabetic Mice," <i>Diabetes</i> , 31: 830-833, 1982 (XP-008023566)
BA		Assan, R. et al., "Dehydroepiandrosterone (DHEA) for Diabetic Patients?" <i>European Journal of Endocrinology</i> , 135: 37-38, 1996 (XP-008023704)
BB		Buffington, C. et al., "Case Report: Amelioration of Insulin Resistance in Diabetes With Dehydroepiandrosterone," <i>Am. J. Med. Sci.</i> , 306(5): 320-324, 1993 (XP-008023722)
BC		Holmes, M. et al., "Phenotypic analysis of mice bearing targeted deletions of 11 β -Hydroxysteroid Dehydrogenases 1 and 2 Genes," <i>Molecular and Cellular Endocrinology</i> , 171: 15-20, 2001 (XP-001149391)
BD		Walker, B., "Steroid Metabolism in Metabolic Syndrome X," <i>Best Practice & Research Clinical Endocrinology & Metabolism</i> , 15(1): 111-122, 2001 (XP-009015671)
BE		Livingstone, D. et al., "Mechanisms of Dysregulation of 11 β -Hydroxysteroid Dehydrogenase Type 1 in Obese Zucker Rats," <i>J. of Endocrinology</i> , 167: 533-539, 2000 (XP-008015658)
BF		Walker, B. et al., "Increased Glucocorticoid Activity in Men with Cardiovascular Risk Factors," <i>Hypertension</i> , 31: 891-895, 1998 (XP-001149397)
BG		Watson, R. et al., "Dehydroepiandrosterone and Diseases of Aging," <i>Drugs and Aging</i> , 9(4): 274-291, 1996 (XP-008015849)
BH		Mukasa, K. et al., "Dehydroepiandrosterone (DHEA) Ameliorates the Insulin Sensitivity in Older Rats," <i>J. Steroid Biochem. Molec. Biol.</i> , 67(4): 355-358, 1998 (XP-002259535)
BI		Kotelevtsev, Y. et al., "11 β -Hydroxysteroid Dehydrogenase Type 1 Knockout Mice Show Attenuated Glucocorticoid-Inducible Responses and Resist Hyperglycemia on Obesity or Stress," <i>Proc. Natl. Acad. Sci. USA</i> , 94: 14924-14929, 1997 (XP-002220014)
BJ		Walker, B. et al., "Carbenoxolone Increases Hepatic Insulin Sensitivity in Man: A Novel Role for 11-Oxosteroid Reductase in Enhancing Glucocorticoid Receptor Activation," <i>J. Clin. Endocrinol. Metab.</i> , 80: 3155-3159, 1995 (XP-000612666)
BK		Jamieson, P. et al., "Interactions Between Oestradiol and Glucocorticoid Regulatory Effects on Liver-specific Glucocorticoid-inducible genes: possible evidence for a role of hepatic 11 β -Hydroxysteroid Dehydrogenase Type 1," <i>J. of Endocrinology</i> , 160: 103-109, 1999 (XP-008015659)
BL		Stewart, P. et al., "Growth Hormone, Insulin-Like Growth Factor-1 and the Cortisol-Cortisone Shuttle," <i>Hormone Research</i> , 56: 1-6, 2001 (XP-008015663)

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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CJ		Database Accession No. 135: 267339 (XP-002241945)
	CK		Database Accession No. 97: 207991 (XP-002241943)
	CL		Database Accession No. 103: 153804 (XP-002241944)
	CM		Database Accession No. EMB-1999324319 (XP-002259536)
	CN		Abadie, J., "Effects of Dehydroepiandrosterone on Fatty Acid Profiles in Zucker Rats: Evidence for Decreasing Insulin Resistance," <i>Dissertation Abstracts International</i> , 60(7): page 3215, 1999 (XP-008015870)
	CO		Andrews, R. et al., "Abnormal Glucocorticoid Metabolism and Sensitivity in Type 2 Diabetes Mellitus," <i>Journal of Endocrinology</i> , 163: page 28, 1999 (XP-008015657)
	CP		Walker, B., "Cortisol Secretion and Sensitivity in Insulin Resistance," <i>Journal of Endocrinology</i> , 160: page S37, 1999 (XP-008015770)
	CQ		Hermanowski-Vosatka, A. et al., "PPAR α Agonists Reduce the Expression of 11 β HSD1 in the Liver," <i>Journal of Endocrinology</i> , 164: page 283, 2000 (XP-008015933)
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